THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

1. What is the National Vaccine Injury Compensation Program (VICP)?

The National Childhood Vaccine Injury Act of 1986 (the ACT) established the VICP. This Program went into effect in October 1988 and is a Federal "no-fault" system designed to compensate those individuals, or families of individuals, who have been injured by childhood vaccines, whether administered in the private or public sector.

2. What vaccines are covered?

Diphtheria, tetanus, pertussis (DTP, DTaP, DT, TT, or Td), **measles, mumps, rubella** (MMR or any components), and **polio** (OPV or IPV).

Effective August 6, 1997, **hepatitis B, *Haemophilus influenzae* type b**, and **varicella** vaccines have been added for coverage under the Program. Eight years' retroactive coverage will be provided for vaccine-related adverse events associated with these three new vaccines.

3. How are new vaccines added for coverage under the Program?

On March 24, 1997, a final rule was published which, in part, provided for the "automatic" addition of future vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. However, Congress will still need to set an appropriate excise tax on any new vaccines recommended by CDC before those vaccines are effectively covered under the Program. Under the current statutory language, 8 years' retroactive coverage will be provided for those claiming injury or death resulting from a vaccine newly added to the VICP.

4. Who may file a claim?

A claim may be made for any injury or death thought to be a result of a covered vaccine. These injuries may include, but are not limited to: **anaphylaxis, paralytic polio**, and **encephalopathy**. The injured individual may file; or a parent, legal guardian, or trustee may file on behalf of a child or an incapacitated person.

5. What is the time frame in which to file a claim?

For injuries resulting from a vaccine administered **on or after October 1, 1988**, the following restrictions apply:

a. In the case of an injury, the effects must have continued at least 6 months after vaccine administration and the claim must be filed within 36 months after the first symptoms appeared.

b. In the case of a death, the claim must be filed within 24 months of the death and within 48 months after the onset of the vaccine-related injury from which the death occurred.

The time for filing claims for injuries resulting from vaccines administered **prior to October 1, 1988,** has expired. Any claims filed for that time period are subject to dismissal by the U.S. Court of Federal Claims (the Court).

6. Whom can I contact to get more information about the Program?

a. The National Vaccine Injury Compensation Program Internet Home Page can be found at the following address:

http://www.hrsa.dhhs.gov/bhpr/vicp

b. The toll-free number for the National Vaccine Injury Compensation Program is **1-800-338-2382** to obtain an information packet detailing how to file a claim, criteria for eligibility, and the documentation required. For further information write to:

National Vaccine Injury Compensation Program
Parklawn Building, Room 8A-35
5600 Fishers Lane
Rockville, Maryland 20857

c. For information on the rules of the U.S. Court of Federal Claims, including requirements for filing a petition, call **1-202-219-9657** or write to:

U.S. Court of Federal Claims
717 Madison Place, N.W.
Washington, D.C. 20005

7. How is the VICP funded?

Funding of vaccine claims **depends on the date of vaccination**:

a. For vaccines administered prior to October 1, 1988, awards are compensated from Federal tax dollars allocated by Congress at $110 million per year.

b. For vaccines administered on or after October 1, 1998, awards are paid from the Vaccine Injury Compensation Trust Fund, funded from an excise tax on every dose of covered vaccine that is purchased.

8. How does the VICP work?

The Program is administered jointly by the Court, the Department of Health and Human Services (HHS), and the Department of Justice (DOJ). The process is as follows:

a. An individual claiming injury from a vaccine files a petition for compensation with the Court;

b. A physician at the Division of Vaccine Injury Compensation, HHS, reviews each petition to determine whether it meets the criteria for compensation. This recommendation is provided to the Court through a report filed by the DOJ, although it is not binding.

c. The HHS position is represented by an attorney from the DOJ in hearings before a "special master" who makes the initial decision for compensation under the Program. A special master is an attorney appointed by the judges of the Court.

d. Decisions may be appealed to the Court and then to the Federal Circuit Court of Appeals.

9. How is eligibility for compensation determined?

There are three means to qualify for compensation:

a. A petitioner must show that an injury found on the Vaccine Injury Table occurred; or

b. A petitioner must prove that the vaccine caused the condition; or

c. A petitioner must prove that the vaccine significantly aggravated a pre-existing condition.

The Vaccine Injury Table lists specific injuries or conditions and the time frames in which they must occur after vaccine administration. The Table is a legal mechanism for defining complex medical conditions and allows a statutory "presumption of causation." It is much

easier to demonstrate a "Table Injury" than to prove that the vaccine caused the condition, and most claims allege that a Table Injury occurred. Compensation is not awarded, however, if the Court determines that the injury or death was due to a cause unrelated to the vaccine, even if it was a Table Injury.

In contrast to civil liability suits, hearings to determine eligibility under the VICP usually last only 1 or 2 days. A case found eligible for compensation is scheduled for a hearing to assess the amount of compensation. Most claims found to be noncompensable receive awards for attorney's fees and costs.

10. How many claims have been received by the Program and which vaccines are most commonly involved?

As of July 31, 1997, a total of 5,169 petitions have been filed. The breakdown by vaccine is as follows:

DTP:	73%	Tetanus/Td/DT:	1%
MMR or components:	14%	Other*:	2%
IPV or OPV:	10%		

*Vaccines not covered under the Program or unspecified vaccines.

11. What is the amount of an award under the VICP?

Awards to the estate in a vaccine-related death are limited to $250,000 plus attorney's fees and costs. Awards to individuals with an injury judged to be vaccine-related have averaged $593,566 although this amount typically represents the cost of an annuity that pays out significantly more over the life of the petitioner. There is no limitation as such on the amount of an award in a vaccine-related injury; however, the law does contain certain restrictions.

12. How does the VICP protect vaccine administrators and vaccine manufacturers?

a. For vaccine administrators and manufacturers: The Act requires that vaccine injury claims involving covered vaccines given on or after October 1, 1988, must first be filed with the VICP before civil litigation through the tort system can be pursued. If a petitioner accepts an award under the VICP, the claim cannot be brought subsequently to the tort system.

b. For vaccine manufacturers: In addition to the above, the legislation sets new, more restrictive standards for actions alleging injury from these covered vaccines in cases that are brought to the tort system.

13. Under what circumstances may a vaccine administrator or manufacturer be sued?

a. If the petition has been judged non-compensable or dismissed under the VICP, or

b. If the award granted by the VICP is otherwise rejected by the petitioner, or

c. If the vaccine is not covered under the VICP.

14. Have there been changes to the Vaccine Injury Table?

On March 10, 1995, a modified Vaccine Injury Table (and the accompanying Qualifications and Aids to Interpretation) became effective for all claims filed on or after that date. Significant changes include the addition of chronic arthritis under vaccines containing rubella (e.g., MMR, MR, R vaccines), and the removal of Residual Seizure Disorder and Hypotonic-Hyporesponsive Episode (HHE) under the DTP vaccine. The definition of Encephalopathy was clarified in the Qualifications and Aids to interpretation.

On March 24, 1997, further modifications to the Vaccine Injury Table took effect that include addition of brachial neuritis and removal of encephalopathy for tetanus-containing vaccines, addition of thrombocytopenia and vaccine-strain measles virus infection, removal of residual seizure disorder for measles-containing vaccines, and addition of vaccine-strain poliovirus infection for live polio virus vaccine. Modifications also include the addition of three new vaccines: hepatitis B, *Haemophilus influenzae* type b, and varicella. The Rule also provides for "automatic" addition of future vaccines recommended by CDC for routine administration to children, although injuries for such vaccines will be specified only after additional rulemaking. Coverage for the three new vaccines went into effect August 6, 1997. All other Table changes became effective for all claims filed on or after March 24.

15. What documentation are vaccine administrators required to keep?

The National Childhood Vaccine Injury Act requires that the date of administration; vaccine manufacturer; lot number; and name, address, and title of the health care provider be recorded in the patient's permanent medical record.

16. What adverse events are health care providers required to report?

The **Vaccine Adverse Events Reporting System (VAERS)**, operated by the Food and Drug Administration (FDA) and the CDC, should be notified of any adverse event by

completing a VAERS reporting form. The following events are required to be reported:

a. Any event set forth in the Vaccine Injury Table that occurs within the time period specified or within 7 days, if that is longer.

b. Any contraindicating event listed in the manufacturer's package insert.

In addition, VAERS accepts all reports by an interested party of real or suspected adverse events occurring after the administration of any vaccine.

The VAERS form may be obtained by calling **1-800-822-7967**.

Reference: Atkinson, W., Furphy, L, Humiston, S., Pollard, B., Nelson, R., Wolfe, C. (ed.), September 1997. Epidemiology and Prevention of Vaccine-Preventable Diseases. 4th ed. Centers for Disease Control and Prevention, Atlanta, GA.